DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
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WARNING LETTER

CIN-05-25746-15

VIA FEDERAL EXPRESS

July 8, 2005

Abe L. Miller, President
Holmes By-Products Company, Inc.
3175 TR 411
Millersburg, OH 44654

Dear Mr. Miller:

A Food and Drug Administration (FDA) investigator conducted an inspection of your rendering facility on March 28, 2005 and April 5-7, 2005. This inspection revealed significant deviations from the regulations set forth in Title 21, Code of Federal Regulations, Part 589.2000 (21 CFR 589.2000), Animal Proteins Prohibited in Ruminant Feed. That regulation is intended to help prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE).

Our investigator observed the following conditions:

The failure to use clean-out procedures or other means adequate to prevent carryover of protein derived from mammalian tissues to animal protein or feeds that may be used for ruminants. For example, the investigator observed:

- Visible build-up of raw materials on the walls of the raw material room, raw materials bin and on the sides of the pre-breaker conveyor.
- Heavy accumulation of meal dust on the silos, augers, elevators, hammer mill, shaker screen and chute, truck loading chute and over-head pipes in the truck loading area.
- Solidified build-up on the auger chutes including the auger leading to the hammer mill.

The failure to maintain procedures for separating products that may contain protein derived from mammalian tissues from all other protein products, from the time of receipt until the time of shipment. For example:

- Poultry meal and prohibited meat and bone meal may be expelled directly onto the floor when the hammer mill is not operating and there is no procedure to clean the floor if meat and bone meal is processed first.

The failure to maintain records sufficient to track the manufacture of products that may contain protein derived from mammalian tissues throughout their receipt, processing and distribution. For example,

- 50% of records do not document that the cookers and conveyors were emptied after prohibited material had been processed.
- Approximately 95% of the production sheets reviewed dating back to August 2004 do not document the last material processed before processing poultry material, the time the poultry material entered the cooker, the time the poultry started to expel from the system (beginning flush), or the time the lever was switched to the poultry silo (ending flush).

As a result of these deviations from 21 CFR Part 589.2000, the chicken by-product meal that you manufacture may contain mammalian proteins prohibited in ruminant feed. Because you have failed to label a product that may contain prohibited materials with the required cautionary statement **"Do not feed to Cattle or Other Ruminants,"** the chicken by-product meal is misbranded under Section 403(a)(1) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. § 343(a)(1)].

This letter is not intended to be an all-inclusive list of deficiencies at your facility. As a manufacturer of materials intended for animal feed use, you are responsible for ensuring that your overall operation and the products you manufacture and distribute comply with the law. You should take prompt action to correct these violations, and you should establish a system whereby violations do not recur. Failure to promptly correct these violations may result in regulatory action, such as seizure and/or injunction, without further notice.

You should notify this office in writing within 15 working days of receiving this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the violations and prevent their recurrence. If corrective action cannot be completed in 15 days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Your reply should be directed to Stephen J. Rabe, Compliance Officer, U.S. Food and Drug Administration, 6751 Steger Drive, Cincinnati, OH 45237, telephone (513) 679-2700, extension 163.

Sincerely,

Carol A. Heppe
District Director

Cc: Dennis Koshmider, Vice President General Manager